Notice of Allowability	Application No.	Applicant(s)	
	10/821,283	HARDY ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *November 17, 2005*.

2. ☒ The allowed claim(s) is/are *1-4, 7, 8, 11-13, 17-20, 25--27, 30, 32, 33, 37-46*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 4/2004; 2/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

This Notice of Allowability is in response to Applicant's election with traverse of Group III, Claims 1-10, 25, and 33, in the reply filed on November 17, 2005. The traversal is on the ground(s) that the search for the DNA encoding the elected peptides and methods of using the peptides would not be an undue burden for the Examiner. In this particular instance, search of the peptide did not provide art against the elected invention, and the Examples in the specification provide enablement for the elected peptides. Therefore, the search of the peptides was adequate to determine the art for the DNA encoding the peptides. Thus, claims 1-36 as amended in the paper filed November 17, 2005 have been examined.

The requirement is still deemed proper and is therefore made FINAL.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allan A. Fanucci on January 12, 2006.

Examiner's Amendments to the Claims:

Please make the following Examiner's Amendments to the claims:

1. (Currently Amended) [A] An isolated peptide comprising at least one epitope that is recognized by and binds to a BAT monoclonal antibody, said peptide selected from the group consisting of:

(a) a peptide having the sequence of any one of SEQ ID NOs: 11 through 16;

(b) a [homolog] peptide having at least 70% identity with a peptide of (a)[and retains the biological activity thereof];

(c) a fragment of a peptide of (a) or (b)[having the biological activity

thereof]; and

(d) [a variant, derivative or salt of a peptide of (a), (b) or (c) which retains the biological activity thereof; and

(e)] a combination of peptides according to (a), (b), or (c)[or (d)].

2. (Currently Amended) The peptide according to claim 1, wherein [the] said peptide is selected from the group consisting of:

(a) a peptide having the sequence of any one of SEQ ID NOs: 14 or 16;

(b) a [homolog] peptide having at least 70% identity with a peptide of (a)[and retains the biological activity thereof];

(c) a fragment of a peptide of (a) or (b)[having the biological activity thereof]; and

(d)[a variant, derivative or salt of a peptide of (a), (b) or (c) which retains the biological activity thereof; and

(e)] a combination of peptides according to (a), (b), or (c) [or (d) which retains the biological activity thereof].

3. (Currently Amended) [A] The peptide according to claim 1, wherein said peptide is capable of inhibiting binding of BAT monoclonal antibody to lymphoma cells.

4. (Original) The peptide according to claim 3, wherein the lymphoma cells are Daudi or Jurkat cells.

5. (Cancelled)

6. (Cancelled)

7. (Currently Amended) [A] An isolated peptide [useful for] capable of inhibiting tumor growth, said peptide selected from the group consisting of:

(a) a peptide having the sequence of any one of SEQ ID NOs: 11 through 16;

(b) a [homolog] peptide having at least 70% identity with a peptide of (a)[and retains the biological activity thereof];

(c) a fragment of a peptide of (a) or (b)[having the biological activity thereof]; and

(d) [a variant, derivative or salt of a peptide of (a), (b) or (c) which retains the biological activity thereof; and

(e)] a combination of peptides according to (a), (b), or (c)[or (d)].

8. (Currently Amended) The peptide according to claim 7, wherein the peptide is selected from the group consisting of:

(a) a peptide having the sequence of any one of SEQ ID NOs: 14 or 16;

(b) a [homolog] peptide having at least 70% identity with a peptide of (a)[and retains the biological activity thereof];

(c) a fragment of a peptide of (a) or (b)[having the biological activity thereof]; and

(d)[a variant, derivative or salt of a peptide of (a), (b) or (c) which retains the biological activity thereof; and

(e)] a combination of peptides according to (a), (b), or (c) [or (d) which retains the biological activity thereof].

9. (Cancelled)

10. (Cancelled)

11. (Currently Amended) [A] An isolated polynucleotide encoding at least one peptide [recognized by a BAT monoclonal antibody,] according to claim [1] 7.

12. (Currently Amended) The polynucleotide according to claim 11, said polynucleotide having a sequence selected from the group consisting of SEQ ID NOs: 26 through 31.

13. (Currently Amended) The polynucleotide according to claim 11, said polynucleotide having a sequence selected from the group consisting of SEQ ID NOs: 29 and 31.

14. (Cancelled)

15. (Cancelled)

16. (Cancelled)

17. (Currently Amended) A vector comprising [a] the polynucleotide [according to claim 11 encoding at least one peptide] according to claim 37[recognized by a BAT monoclonal antibody].

18. (Currently Amended) The vector according to claim [17] 37, wherein the polynucleotide comprises a sequence selected from SEQ ID NOs: 26 through 31.

19. (Currently Amended) The vector according to claim [17] 37, wherein the polynucleotide comprises a sequence selected from SEQ ID NOs: 29 and 31.

20. (Original) The vector according to claim 17, wherein the vector is a plasmid or a virus.

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

24. (Cancelled)

25. (Currently Amended) A [pharmaceutical] composition comprising as an active ingredient at least one peptide according to claim [1] 7 and a pharmaceutically acceptable carrier.

26. (Currently Amended) A [pharmaceutical] composition comprising as an active ingredient a polynucleotide according to claim 11[and a pharmaceutically acceptable carrier].

27. (Original) A method for treating cancer in a subject in need thereof comprising the step of administering a therapeutically effective amount of a composition according to claim 25.

28. (Cancelled)

29. (Cancelled)

30. (Currently Amended) An immunomodulatory vaccine comprising at least one peptide according to claim [1] Z, [wherein the peptide is recognized by a BAT monoclonal antibody] and a pharmaceutically acceptable adjuvant.

31. (Cancelled)

32. (Original) The vaccine according to claim 30, wherein the adjuvant is selected from the group consisting of an aluminum salt and an oil in water emulsion.

33. (Currently Amended) A diagnostic agent for detecting cancer comprising a peptide[recognized by a BAT monoclonal antibody,] according to claim [1] Z.

34. (Cancelled)

35. (Cancelled)

36. (Cancelled)

37. (New) An isolated polynucleotide encoding at least one epitope according to claim 1.

38. (New) A host cell comprising a vector according to claim 44.

39. (New) A composition comprising as an active ingredient at least one epitope according to claim 1 and a pharmaceutically acceptable carrier.

40. (New) A method for treating cancer in a subject in need thereof comprising the step of administering a therapeutically effective amount of a composition according to claim 39.

41. (New) An immunomodulatory vaccine comprising at least one epitope according to claim 1.

42. (New) A diagnostic agent for detecting cancer comprising at least one epitope according to claim 1.

43. (New) A host cell comprising the vector of claim 17.

44. (New) A vector comprising the polynucleotide of claim 11.

45. (New) The vector according to claim 44, wherein the vector is a plasmid or a virus.

46. (New) The vaccine according to claim 41, wherein the adjuvant is selected from the group consisting of an aluminum salt and an oil in water emulsion.

Examiner's Amendments to the Specification:

At page 1, add the following sentence to the paragraph under "CROSS-REFERENCE TO RELATED APPLICATIONS":

--- The PCT claims foreign priority to Israeli Application IL145926. ---

The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest SEQ ID NOs: 11-16, or that these sequences would be recognized or bind to BAT monoclonal antibody. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER